IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re:	Invention:	INGESTION OF HYALURONIC ACID FOR IMPROVED JOINT HEALTH
	Inventors:	LENEAU, Harry
	Serial No.:	10/629,880
	Filed:	July 29, 2003
	Art Unit:	1615
	Examiner:	HAWES, Pili Asabi
	Confirmation No:	5579
	Our Docket No.:	P00903-US-01 (21934.0001)

DECLARATION OF PRIOR INVENTORSHIP IN THE UNITED STATES (37 C.F.R. § 1.131)

I, Harry Leneau, individually declare as follows:

1. I am the inventor of the subject matter described in the above-identified patent application.

2. Attached to this Declaration is a report (the "Report") entitled "ORAL HYALURONIC ACID (HA) FIELD STUDY FOR POSSIBLE EFFICACY" by Steven C. Allday, DVM, from November 5, 1999, regarding an arthritis evaluation of horses by orally administering hyaluronic acid. The Report contains information corresponding to the subject matter in the above-identified patent application.

3. Prior to the submission of the Report, I provided Dr. Allday with the hyaluronic acid and the instructions to perform the animal studies referenced within the Report.

4. The Report states that "[t]he HA utilized in this evaluation was according to specifics outlined by Amervet Labs Inc." I am the founder of Amervet Labs Inc.

5. The Report was submitted to me from Dr. Allday and was not publicly available prior to the time of filing the above-referenced patent application. Dr. Allday performed the animal studies at my request and direction, and the studies were performed for me by Dr. Allday in confidence.

6. Accordingly, the Report shows that the subject matter described in the above-identified patent application was conceived and reduced to practice at least by the date November 5, 1999, which is a date earlier than the effective date of U.S. Patent No. 6,924,273, namely October 3, 2000. Additional animal studies to determine efficacy and confirm dosing ranges were diligently pursued up to and after the date of filing U.S. Patent Application No. 09/860,426 on May 18, 2001, of which the above-identified application claims priority.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. I further declare that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both (under Section 1001 of Title 18 of the United States Code), and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

INVENTOR:

Harry Leneau

Harry Leneau

11-3-2006

Date

ORAL HYALURONIC ACID (HA)

FIELD STUDY FOR POSSIBLE EFFICACY

S.C.Allday DVM

November 5, 1999

Methods: Horses with known arthritis problems were identified and evaluated for use in an arthritis evaluation using oral hyaluronic acid. The HA used in this evaluation was according to specifics outlined by Amervet Labs Inc. The HA utilized in this evaluation was molecular weight of greater 2.0 million Daltons. The amount given daily was started at 5mg per day. Clinical response was evaluated weekly with the two equine patients given a physical examination to determine lameness associated with known arthritic problems. These horses were jogged on asphalt and given scores varying from 1 to 5. 1 being slight noticeable lameness to 5 being non weight bearing. Both horses are retired show horses that have front fore feet shod every 5 weeks.

Observations: Both horses had long standing demonstrable lameness that have been clinically diagnosed via peripheral and intra-articular blocks as well as radiography to confirm the diagnosis. Both horses were kept in a paddock where they were visually monitored daily for normal health issues (normal behavior, food and water intake, injuries and other possible disease processes)

Weekly evaluations were very routine and simply involved a handler jogging each horse on asphalt and recording the degree of lameness. The only time either of these horses were removed from the weekly evaluations was when they had foot abscesses and the source of the lameness could not be determined. During those periods the horse was treated with non-steroidal anti-inflammatory medication (phenylbutazone) and the foot soaked in hot water and Epsom salts until the peripheral pulse was considered normal in that limb.

The initial dosage of 5mg was maintained for 42 days, 10 mg for 44 days, 20 mg for 28 days 40 mg for 34 days, 60 mg for 28 days and 75 mg for 27 days. All of the oral doses were maintained with increases for consecutive days even when a horse was excluded with treatment for a foot abscess.

Summary: The long process of treating and evaluating this method of administration did yield fairly demonstrable results to improve lameness but only when given much higher doses than originally proposed. Oral administration was much more convenient and much less troublesome than I.V. injections or intra-articular injections. Horses accepted the oral doses easily without resistance even when the volumes increased. (5mg/ml solution) Initial doses were 1ml/day and last doses were 15 mls/day.

Conclusions: Oral administration of hyaluronic acid solution appears to be an effective and highly convenient method of administration to relieve symptoms of osteo-arthritis. Further studies will be necessary with larger sample groups in order to provide adequate statistical data for proper analysis.